II. REMARKS

A. Status of the claims:

Claims 1, 5-28, 31-34, and 38-61 are currently pending. Claims 1, 19, 26, 27, and 38 have been amended without prejudice. Support for the amendments to claims 1, 19, and 38 can be found e.g., at page 42, line 23 to page 43, line 3; page 46, lines 12 to 15; and throughout the specification. New claims 58-61 have been added. Support for new claims 58-60 can be found at page 8, lines 20 to page 9, line 22, and throughout the specification. Support for new claim 61 can be found e.g., at page 42, line 23 to page 43, line 3, the original claims, and throughout the specification. Claims 29 and 30 have been canceled without prejudice.

B. Rejections Under 35 U.S.C. § 102

1. Roos et al. (U.S. Patent No. 5,840,338)

In the Office Action, claims 1, 5, 6, 13-19, 21, 25-30, 33, 38-40, 43-53, 55 and 56 were rejected "as being anticipated by Roos et al. (U.S. 5,840,338).

This rejection is traversed. It is respectfully submitted that Roos et al. fail in the very least to teach a composition as recited in independent claims 1 and 38 which form a hydrogel matrix after injection into a mammal such that the at least one therapeutic agent is released in a controlled manner from said hydrogel matrix.

Further, Roos et al. fail to teach a method for preparing a pharmaceutical composition of independent claim 19, wherein the cross-linked matrix is formed after injection of said composition into a mammal.

Therefore, the Examiner is respectfully requested to remove the 35 U.S.C. §102 rejection of claims over Roos et al.

2. Grinstaff et al. (U.S. Patent No. 5,948,421)

In the Office Action claims 1, 5-7, 9, 11-21, 23, 25-30, 33, 34, 38-40, 43-47, 49-53, 55 and 56 were rejected under 35 U.S.C. §102 (b) as being anticipated by Grinstaff.

It is respectfully submitted that Grinstaff et al. also fail in the very least to teach a composition as recited in independent claims 1 and 38 which form a hydrogel matrix after injection into said mammal. Further, it is respectfully submitted that Grinstaff et al. fail to teach a matrix comprising the oil and aqueous phase emulsion called for in claims 1 and 38, as the polymeric shell of Grinstaff et al. is not a matrix, nor could it be considered to be part of an emulsion. In Grinstaff et al. wherein the therapueutically active agent is contained in an oil phase within the polymer shell (See Grinstaff, et al. at column 9, lines 23-46), the therapeutically active agent would be contained inside the polymeric shell, and would not be physically entrapped within a hydrogel matrix.

Additionally, Grinstaff et al. fail to teach a method for preparing a pharmaceutical composition of independent claim 19, wherein the cross-linked matrix is formed after injection of said composition into a mammal. Further Grinstaff et al. fail to teach an emulsion containing a matrix which is formed in step (ii) of claim 19.

Therefore, the Examiner is respectfully requested to remove the 35 U.S.C. §102 rejection of claims over Grinstaff et al.

3. Yanaki et al.

Claims 1, 38, 40 and 43-51 were again rejected under 35 U.S.C. 102(b) "as being anticipated by Yanaki et al. (U.S. 5,538,728)."

This rejection is traversed. Similar to Roos et al. it is respectfully submitted that Yanaki et al. fail in the very least to teach a composition as recited in independent claims 1 and 38 which form a hydrogel matrix after injection into a mammal.

Therefore, the Examiner is respectfully requested to remove the 35 U.S.C. §102(b) rejection of the claims over Yanaki et al.

C. Rejection Under 35 U.S.C. § 103

1. Roos et al. (U.S. Patent No. 5,840,338)

In the Office Action, claims 31 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Roos et al. (U.S. 5,840,338).

This rejection is traversed. It is respectfully submitted that Roos et al. fail to teach or suggest a method for preparing a pharmaceutical composition of independent claim 19, wherein the cross-linked matrix is formed after said composition is injected into a mammal.

As claim 31 and 32 ultimately depend from claim 19, the Examiner is respectfully requested to remove the 35 U.S.C. §103 rejection of the claims over Roos et al.

D. Rejection Under 35 U.S.C. § 112

In the Office Action, claims 1, 5-34 and 38-57 were rejected under 35 U.S.C. §112, first paragraph, for written description. The Examiner notes that "Claims 1, 19, 38, 54 and 57 recite polyamino acid and the specification does not list any polyamino acid that may be useful in the invention."

This rejection is traversed. It is respectfully submitted that polyamino acids are known in the art and one of ordinary skill in the art would understand which polyamino acids would be suitable for use in accordance with the specification. The Examiner is reminded that what is well known to one of ordinary skill in the art need not be disclosed in detail in the specification. See MPEP 2163 (Eighth Edition Rev. 2), *citing Hybritech*

Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). Further, if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See MPEP 2163 (Eighth Edition, Rev. 2), *citing Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116.

Therefore, it is respectfully submitted that as polyamino acids are well known to one of ordinary skill in the art, Applicants are not required to disclose in detail every polymer which would be encompassed by the claim. Applicants have provided certain representative examples of the formulations in the present application, and have stated in the specification a number of different polymers useful in accordance with the present invention.

In view of the above, the Examiner is respectfully requested to the Examiner is respectfully requested to remove the 35 U.S.C. §112, first paragraph rejection of the claims.

With respect to the Examiner's question regarding the polymer formed from α,ω-dihydroxy-poly (ethylene glycol) or α,ω-diamino-poly (ethylene glycol) or a polymer that is the product of α,ω-dihydroxy-poly(ethylene glycol) and thiomalic acid or and α,ω-diamino-poly (ethylene glycol) and thiomalic acid or α,ω-dicarboxy-PEG-subunits and lysine, it is respectfully submitted that one of ordinary skill in the art would know the polymers formed in view of the specification at e.g., pages 7, lines 18 to page 8, line 3; page 28, line 7 to page 29, line 9, and the Examples.

E. <u>Inventorship</u>

Applicants note the Examiner's acknowledgement of the Applicants' previous communication regarding the addition of an inventor. Applicants are currently in the process of obtaining the necessary forms for the change of inventorship and will forward them to the Examiner upon receipt.

III. CONCLUSION

In view of the actions taken and arguments presented, it is respectfully submitted that reconsideration of the amended claims and withdrawal of the previous rejection is warranted.

An early allowance is earnestly sought. Should a discussion aid in furthering the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided below.

Respectfully submitted,
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